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CITATIONS

In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 274

PASADENA RESEARCH LABORATORIES, INC., A CORPORATION, AND RUSSELL R. BAVOUSET, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (R. 234-259) has not yet been reported.

JURISDICTION

The judgment of the Court of Appeals was entered July 16, 1948 (R. 260). On August 10, 1948, Chief Justice Vinson granted an extension of time to September 14, 1948, to file a petition for a writ of certiorari. The petition was filed September 13, 1948. The jurisdiction of this Court

is invoked under 28 U.S.C. 1254(1). See also Rules 37(b)(2) and 45(a), F.R. Crim. P.

QUESTION PRESENTED

Whether, in a prosecution for introducing adulterated and misbranded drugs into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act of 1938, it is necessary for the Government to disprove every conjectural suggestion as to extraordinary handling the products might have received from the time they were originally shipped to the time they were examined by Government chemical analysts, there being no evidence that they were handled in any way other than the usual course of business.

STATUTE INVOLVED

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 676, 52 Stat. 1040, 21 U.S.C. 301 et seq., provides in part:

> SEC. 201. For the purposes of this Act—
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> * * * * * *
>
> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the condi-

tions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

* * * * * *

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine * * *.

* * * * *

SEC. 501. A drug or device shall be deemed to be adulterated—

* * * * * *

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

* * * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

STATEMENT

A seven count information, charging interstate shipments of misbranded and adulterated drugs,

in violation of the Federal Food, Drug, and Cosmetic Act, was filed against petitioners in the District Court for the Southern District of California (R. 2-12). Petitioners waived a jury trial (R. 17) and they were found guilty by the court and sentenced on counts 1, 2, 3, 4 and 7, and were acquitted on counts 5 and 6 (R. 20-21). The interstate shipments were admitted by stipulation (R. 14). The Government's evidence as to the various counts may be summarized as follows:

Counts 1 and 2. These counts charged that petitioners introduced into interstate commerce a quantity of an adulterated (count 1) and misbranded (count 2) drug called "Sterile Indoform," the labels of which represented that each cubic centimeter contained three International Units of posterior pituitary and one grain of thyroid substance, whereas in fact the drug contained no thyroid substance and less than three units of posterior pituitary (R. 2-5). Petitioner Bavouset admitted that the drug contained such small quantities of posterior pituitary as to be immeasurable (R. 143-144). Arnold E. Mason testified that on February 18, 1946, as part of his duties as a pharmacologist and analyst with the Food and Drug Administration in Washington, D. C. (R. 57), he analyzed samples of the drug which a Food and Drug Inspector had previously collected from the doctor in Cheyenne, Wyoming, to whom petitioners had shipped a number of vials

on September 17, 1945 (R. 59, 14). Using the accepted tests (R. 80-82), he ascertained that the drug contained no measurable quantity of posterior pituitary (R. 59, 74). He further testified that posterior pituitary would remain stable and continue to be effective for many months and even years (R. 74) unless it is boiled at 212° Fahrenheit for five or six hours (R. 73-74). He stated that when he received the sample, the vial was full and the rubber stopper or cork was protected with a celluloid seal around it, and that it appeared as if it had never been opened (R. 215, 79-80). It was his opinion that at the time of shipment, five months before his analysis, the drug could not have contained three units of posterior pituitary per cubic centimeter (R. 75-76). After conducting his test, without tampering with or adding anything to the product, Mason sent the vial to San Francisco for further analysis (R. 77). Mr. Buell, a chemist with the Food and Drug Administration in San Francisco (R. 84), testified that he analyzed the contents of the vial of Indoform on March 27, 1946 (R. 85-86), and found that it contained no organically combined iodine (R. 89), the distinguishing, active constituent of thyroid (R. 87). He testified that thyroid is an extremely stable substance (R. 89-90), and in his opinion the sample of Indoform he examined could not possibly have contained any organically combined iodine when it was shipped by petitioners (R. 90).

Petitioner Bavouset admitted that the product contained no organically combined iodine (R. 110-111), but contended that the legend on the label that it contained "Thyroid Substance 1 gr." was rendered not misleading by the further statement thereon that (R. 63):

> This preparation does not contain any known therapeutically useful constituent.

Counts 3 and 4. These counts (R. 5-8) involve a shipment of a vitamin product called "Pluri-B," the labels of which represented that each cubic centimeter contained 50 milligrams of thiamine hydrochloride (R. 35). It was stipulated (R. 15) that on or about August 30, 1945, a Food and Drug Inspector had secured a sample of this product from a doctor to whom petitioners had shipped it on or about July 16, 1945, and, after sealing it, had sent it by mail to the Vitamin Division, Food and Drug Administration, Washington, D. C. Dr. Chester D. Tolle, of the Food and Drug Administration in Washington, testified that when he received the sample, the vial appeared to be full and not to have been tampered with (R. 212). He further testified that it is the practice of the Administration to have inspectors make notations on their reports if samples collected by them have been opened, and, in such event, he would not have had the sample analyzed in his laboratory (R. 213). Mr. Capps, a chemist in the Vitamin Division (R. 97), testified that on September 24, 1945 (R.

97), he examined this vial of Pluri-B and found that it contained only 33 milligrams of thiamine hydrochloride per cubic centimeter (R. 99-100). He further testified that in a properly made solution, thiamine hydrochloride is very stable except when exposed to extremely high temperatures (R. 100).

Petitioner Bavouset testified that this product was made in a proper acid base and would substantially retain its potency for a year (R. 131, 149, 151) and that petitioners' products are bottled and sealed by the most improved methods, designed to prevent the entrance of impurities, to protect the contents from light, and to keep the contents in a reasonably good state of preservation (R. 131-132). Bavouset further admitted that at the time this drug was shipped, his laboratory did not have the equipment to make a thiachrome determination for thiamine (R. 144).

Count 7. This count involves a shipment of a sterile solution of Pluri-B, which was alleged to be adulterated by reason of the presence of undissolved matter. It was stipulated (R. 16-17) that the shipment to a doctor was made on or about June 18, 1946, and that on or about July 12, 1946, a Food and Drug Inspector collected a sample, consisting of six vials, from the doctor, and, after sealing it, sent it to the Pharmacology Division, Food and Drug Administration, Washington, D. C., via railway express. Dr. Frank H. Wiley,

Chief of the Chemical Section, Medical Division, Food and Drug Administration (R. 32), testified that he received the sample, with all the vials sealed, capped and full (R. 226), on July 23, 1946, and examined it on August 1, 1946 (R. 33, 38), when he found a considerable quantity of undissolved material visible to the naked eye (R. 34). On June 17, 1947, the date of his testimony, the amount of undissolved material was the same as when he first examined it (R. 37-38). In his opinion, the undissolved material was present on June 18, 1946, the date of the shipment by petitioners (R. 42). Only such an improbable factor as transmitting the sample to Washington in a refrigerator car might have hastened the crystallization if it had not taken place earlier (R. 42). Dr. Wiley testified that the presence of the noted undissolved materials was the result of a supersaturated solution of riboflavin (R. 44) and that the sample contained about twenty times as much riboflavin as may ordinarily be dissolved in a water solution (R. 46). Riboflavin is stable and will remain dissolved if the amount is below the saturation point (R. 44). Although petitioner Bavouset and Dr. Icke, a witness for petitioners, testified that the undissolved material should dissolve if the vial were put in water of about 110°-120° Fahrenheit (R. 145, 190), Dr. Wiley testified that he had placed the vials in warm water of about 150° for ten to fifteen minutes, and that the undis-

solved material remained (R. 226-227). Dr. Clinton H. Thienes testified concerning the dangers inherent in the presence of undissolved material in a sterile solution intended, as this was, for intravenous or intramuscular injection (R. 49-51).

ARGUMENT

Simply stated, petitioners' argument comes down to the contention that the Government was obliged to prove by affirmative evidence that the samples involved were not subjected to extraordinary, highly improbable handling between the time of shipment by petitioners and the time they were analyzed by the Food and Drug experts, although there was not the slightest suggestion of any facts indicating that the products were handled other than in the usual course of business.

Petitioners' argument, if accepted, would require the Government to follow the products through the mails or railway express, tracing them throught the hands of each and every one of the numerous mail clerks, etc., who, undoubtedly unknowingly, may have handled the much larger packages or mail bags in which these samples were anonymously contained. Then too, evidence would be required not only that the doctors who received the drugs did not perform the most unusual operations which might have caused the inadequate conditions which examination of the drugs disclosed, but also that those who may have assisted the doctors, did not irrationally and for

no conceivable reason subject the products to such extraordinary treatment.

As to the Indoform, the evidence was that it would remain stable unless boiled at 212° Fahrenheit for from five to six hours. Petitioner apparently contends that the Government was required to adduce the specific negative testimony of each of the numerous people who might at some time have come in contact with the samples that he did not boil the samples for five or six hours. Further, however, it should be noted that as to counts 1 and 2, petitioner Bavouset admitted that at the time of shipment the Indoform did not contain any of the only active, therapeutically valuable component of thyroid, nor the advertised amount of posterior pituitary. Thus, even acceptance of petitioners' contention would not require reversal of the convictions on counts 1 and 2.

The negative fact which petitioners would require the Government to establish as to the Pluri-B involved in counts 3 and 4 is that none of the innumerable persons who at any time handled the samples subjected them to extremely high temperatures, considerably in excess of those which might be reached in ordinary weather conditions. And this would be required despite petitioners' admission that their laboratory at the time of this shipment did not have the equipment required to make the accepted test for thiamine hydrochloride potency.

And as to the sterile Solution of Pluri-B forming the basis of count 7, petitioners would require the Goverment to prove by affirmative evidence that the samples were not sent by refrigerator car and that other ingredients had not been added to them, although the evidence showed that they were sealed, capped and full upon receipt by the government analysts.

As the court below fully pointed out (R. 244-247), the burden on the Government in a criminal case is to prove all the essential elements of an offense beyond a reasonable doubt; there is no requirement that the Government prove its case beyond any possible doubt which might be raised by sheer speculation and conjecture by ingenious counsel. See *Henderson* v. *United States,* 143 F. 2d 681, 682 (C.C.A. 9); *Rose* v. *United States,* 149 F. 2d 755, 759 (C.C.A. 9); *United States* v. *S. B. Penick & Co.,* 136 F. 2d 413, 415 (C.C.A. 2); and other authorities cited by the court below (R. 244-247). See also, *Bishop* v. *United States,* 107 F. 2d 297, 303 (App. D.C.); *United States* v. *Guthrie,* 171 Fed. 528, 532 (S.D. Ohio); *United States* v. *Dexter,* 154 Fed. 890, 894 (N.D. Iowa); *United States* v. *Reid,* 210 Fed. 486, 490 (D. Del.); *United States* v. *Wilson,* 176 Fed. 806, 809-810 (C.C.S.D. Fla.).

The court below relied upon the wholly unrebutted presumption of regularity in the conduct of normal business affairs on the part of government officers and private individuals. The Food

and Drug employees who made the analyses and examinations of the samples all testified that they handled the products in the normal, ordinary manner. When the vials were first received for analysis, they all were full and appeared not to have been opened (R. 79-80, 215, 212, 213, 226). In the absence of any evidence that they had been tampered with or handled in any manner other than according to the usual course of handling of such commodities, the court reasonably applied the common sense, long-established legal presumption of regularity in the conduct of the government officers and employees and of the private individuals who may have handled the materials. Cf. *United States Bank* v. *Dandridge,* 12 Wheat 64, 69-70; *United States* v. *Chemical Foundation,* 272 U.S. 1, 14-15; *Boerner* v. *United States,* 30 F. Supp. 635, 637 (E. D. N. Y.), affirmed, 117 F. 2d 387 (C.C.A. 2), certiorari denied, 313 U.S. 587; *International Shoe Company* v. *Federal Trade Commission,* 280 U.S. 291, 302; and other cases cited by the court of appeals (R. 247-250).

Appended to petitioners' brief in support of their petition for a writ of certiorari is a copy of an unreported opinion of the District Court for the Southern District of California in *United States* v. *Boyle,* which petitioners argue is in conflict with the decision in the instant case. In the first place, it should be noted that even if the claimed inconsistency were present, it would not

call for review by this Court since to the extent that there might be any conflict, the opinion of the Ninth Circuit here attacked would be controlling.

At any rate, in the instant case the evidence is clear that none of the commodities involved would be adversely affected by conditions normally to be expected in the course of routine transportation and handling. That the government inspectors shipped the samples to the analysts by mail is consistent with the absence of any handling instructions on the label and with petitioners' own use of the mails for shipment (R. 121). The opinion in the *Boyle* case does not disclose that any such evidence was presented as to the commodities there involved.

Finally, petitioners argue that the criminal provisions of the statute should be strictly construed. It is not clear, however, in what respect it is claimed that the statute was not strictly construed. The Act makes it an offense to introduce adulterated or misbranded commodities into interstate commerce. The interstate shipments here were admitted. The facts that the samples were adulterated and were not as represented on the label when analyzed by the government chemists, were undisputed. The trial judge found, as a matter of fact, that the drugs were adulterated and misbranded when shipped by petitioners. Even if the judge's findings of fact were erroneous as not supported by evidence, that circumstance would not demonstrate

that the criminal provisions of the statute had not been strictly construed. There is no claimed ambiguity in the statute, nor is there any question of interpretation of the Act involved. The trial court, sustained by the circuit court of appeals, found facts constituting a violation of the strict, unambiguous terms of the Act. We submit, therefore, that petitioners' contention that the Act should be strictly construed is irrelevant to the situation here presented, which involves simply a matter of evidence.

CONCLUSION

The decision below is correct and no real conflict is involved. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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